DYNAMIC CONNECTING ELEMENT FOR A SPINAL FIXING SYSTEM AND A FIXING SYSTEM COMPRISING SUCH A CONNECTING ELEMENT

[0001] The present invention relates to the field of spinal fixing systems for connecting vertebrae together, more particularly to the field of connecting elements intended to maintain a spacing between at least two anchoring elements implanted respectively in a vertebra.

[0002] There exist currently two types of spinal connections: on the one hand osteosynthesis connections and on the other hand dynamic connections.

[0003] Spinal osteosynthesis connections are well known connections. There are in fact frequently used for consolidating several consecutive vertebrae. Their purpose is to immobilize the vertebrae connected in a particular configuration and to stabilise them during the bone fusion in order to allow fixed stabilisation in the immobilized situation. Such connections consist of rigid rods.

[0004] On the other hand, dynamic connections are used to reduce stresses on the articular facets and on intervertebral discs by allowing certain movements, whilst if necessary realigning the vertebrae with respect to one another.

[0005] The prior art already knows such connecting elements.

[0006] In particular, a device for stabilising adjoining dorsal vertebrae is proposed in the European patent application EP0669109. The said device comprises a connecting element consisting of a band produced from elastic synthetic material and having a round transverse section. This band is intended to be fixed between at least two pedicular screws consisting respectively of a head provided with a transverse piercing. The said band is fixed to the said pedicular screws by inserting, through the transverse piercing, the said band, which is then fixed to each of the said pedicular screws by means of a clamping screw disposed along the axis of the

corresponding screw, that is to say transversely to the piercing. The said device also comprises a support element mounted around the said band in order to form a body resisting pressure.

[0007] Such a connecting element does however have the drawback of not effecting any torsion return in order to oppose pivoting movements of the vertebrae around the discs.

[0008] Another important drawback of this connecting element is that it cannot be curved so as to adapt to the natural lordosis of the lumbar vertebral column.

[0009] In addition, another drawback is that the connecting element occupies a large volume (around 12.5 mm). In some circumstances, it may prove to be difficult to prevent the connecting element in question coming into contact with the bones, such a contact causing a great deal of pain.

[0010] Moreover, such a device has a particularly important drawback relating to the need to choose the length of the support element before fitting the said band. It may happen however that the effective distance between the screws after tensioning the band is not exactly that desired. However, the device as configured allows no freedom of relaxation and/or compression between the screws after the fitting of the band and support element. The surgeon therefore has no other choice than to remove the assembly consisting of support element and band in order to introduce a new support element having a different length.

[0011] There is also proposed, in international patent application WO 02/07621, a connecting piece intended to maintain a spacing between at least two anchoring elements screwed into vertebrae, the said connecting piece comprising: i) a flexible part divided into two continuous branches spaced apart from each other, the said branches being substantially symmetrical with respect to the longitudinal axis of the said piece, the ends of the said branches being connected together in pairs and defining a first mean plane, and ii) two rigid parts forming

rods, having a first fixing portion and a second portion, each said second portion of the said two rigid parts respectively extending in opposite directions the said ends of the said branches connected together in pairs, the cross-section of each of the said branches being less than the cross-section of the said rigid parts so that the said connecting piece, whose fixing portions are fixed respectively to each of the two anchoring elements, is able to bend elastically perpendicular to the said mean plane during the relative movement of the vertebrae, by means of which the vertebrae, kept spaced apart from one another, are able to move with respect to one another.

[0012] This connecting piece does however have the drawback of being able to bend only in one clearly determined direction, namely perpendicular to the mean plane formed by the two branches. The result is a mounting of the whole of the stabilisation system comprising such connecting pieces requiring a certain amount of precision and therefore possibly proving tedious.

[0013] Another drawback of such a connecting piece also proves to be its volume.

[0014] A first object of the invention is to remedy the drawbacks of the dynamic connecting elements described above by proposing a connecting element having an amplitude of flexion equivalent with regard to these dynamic connecting elements but whose holding in rotation is ensured.

[0015] The said connecting element that is the object of the invention also has the advantage of being able to be curved so as to adapt to the natural lordosis of the lumbar vertebral column.

[0016] The said connecting element that is the object of the invention also has the advantage of being not very invasive, whilst providing the functionalities required for a dynamic connecting element (flexibility, resistance to wear, etc).

[0017] The said connecting element also has the advantage of allowing rapid mounting on the anchoring elements fixed to the vertebrae.

[0018] Finally, the said connecting element has the advantage of being able to undergo relaxation and/or compression after its fitting on the anchoring elements.

[0019] To do this, the present invention concerns a connecting element for a spinal fixing system intended to connect at least two implantable connection assemblies, the said connecting element being remarkable in that it consists of a cable and a polymer envelope surrounding the said cable, the said cable consisting of at least one elastic strand coaxial with the said envelope so as to form the core of the connecting element.

[0020] In order not to burden the rest of the description, the said strand forming the core of the said connecting element is defined as the central strand.

[0021] Preferably, the said connecting element comprises at least one layer of at least six strands distributed around the said central strand.

[0022] According to an advantageous configuration of the invention, the said connecting element comprises two layers of successive strands disposed around the said central strand, the first layer of strands surrounding the said central strand consisting of 6 strands, the second layer of strand surrounding the said first layer consisting of 12 strands.

[0023] Advantageously, the strands constituting the layer or layers consist of strands twisted around the said central strand.

[0024] Advantageously, the strands of the layer or layers consist of a material different from that of the said central strand.

[0025] Advantageously, the central strand has a diameter different from that of the strands of the said layer or layers. According to the type of configuration required, it may be less than or greater than that of the strands of the said layers.

[0026] Advantageously, the strands constituting the layer or layers consist of titanium or stainless steel.

[0027] Advantageously, the central strand is tubular.

[0028] Advantageously, the central strand consists of a nickel-titanium alloy, titanium, stainless steel or polymer, such as for example PEEK or polyurethane.

[0029] Advantageously, the said envelope is made from polyurethane or PEEK or consists of a biocompatible fabric.

[0030] A second object of the invention is to propose a connecting element combining the functionalities of a dynamic connecting element with those of an osteosynthesis connecting element. More particularly, the object of the said connecting element is to propose, conjointly with a dynamic connection of at least two vertebrae, the rigid connection of other vertebrae.

[0031] This is because, in the case of the fitting of a multilevel vertebrae fixing and stabilisation system (instrumentation of several vertebrae) it may prove necessary to connect certain vertebrae together by means of a dynamic connection in order to allow certain movements, and on the other hand to connect the other vertebrae so that no movement is allowed during bone fusion (osteosynthesis connection). In current fixing and stabilisation fixings, the dynamic connecting elements are connected to the rigid connecting elements by means of supplementary fixing elements such as dominoes. The use of supplementary pieces has the drawback of increasing the time for mounting the connecting elements on the anchoring elements.

[0032] The present invention therefore relates also to a connecting element for a spinal fixing system, intended to connect at least two implantable connection assemblies, characterised in that it comprises a flexible part extended at one of its ends at least by a rigid part, the said flexible

part comprising a cable at least partly surrounded by a polymer envelope, the said cable consisting of at least one elastic strand coaxial with the said envelope.

[0033] The connecting element thus configured makes it possible to offer dynamic and rigid "connections" for vertebrae without having recourse to supplementary fixing elements.

[0034] This connecting element is defined in the remainder of the description as being a semi-dynamic connecting element.

[0035] Moreover, and the same as previously, in order not to burden the remainder of the description, the said elastic strand is referred to as the "central strand".

[0036] Preferably, the said rigid part has a cavity indented to at least partly receive the said cable, the said cavity being blind or through.

[0037] Advantageously, the said cavity is configured so as to cooperate closely with the said cable.

[0038] Advantageously, the said cavity has a zone widened in the direction of the end receiving the said cable.

[0039] Advantageously, the flexible part is fixed to the said rigid part by adhesive bonding, crimping or welding.

[0040] Preferably, the said cable comprises, preferably, at least one layer of 6 strands, the said strands being distributed around the said central strand. According to one advantageous configuration of the invention, the said cable comprises two layers of successive strands disposed around the said central strand, the first layer of strands surrounding the said central strand consisting of 6 strands, the second layer of strands surrounding the said first layer consisting of 12 strands.

[0041] Advantageously, the strands constituting the layer or layers consist of strands twisted around the said central strand.

[0042] Advantageously, the strands of the layer or layers consist of a material different from that of the said central strand.

[0043] Advantageously, the central strand has a diameter different from that of the strands of the said layer or layers.

[0044] Advantageously, the strands constituting the layer or layers consist of titanium or stainless steel.

[0045] Advantageously, the central strand is tubular.

[0046] Advantageously, the central strand consists of a nickel-titanium alloy, titanium, stainless steel or polymer, such as for example PEEK or polyurethane.

[0047] Advantageously, the said envelope is made from polyurethane or PEEK or consists of a biocompatible fabric.

[0048] The present invention also relates to a spinal fixing system comprising at least two implantable connection assemblies connected by means of at least one or two previously described connecting elements.

[0049] The invention will be understood better with the help of the description given below, purely by way of explanation, of an embodiment of the invention, with reference to the accompanying figures:

- figure 1 illustrates a lateral view in perspective of a dynamic connecting element according to the invention;
- figure 2 illustrates a variant embodiment of the connecting element of figure 1;
- figure 3 illustrates a view in section of the connecting element of figure 2;

- figure 4 illustrates a partial view in perspective of a spinal fixing system comprising rigid connecting elements and dynamic connecting elements according to the invention; and
- figure 5 illustrates a view in section of a semi-dynamic connecting element according to a preferred embodiment of the invention.

[0050] The connecting elements (1) depicted in figures 1 to 4 constitute dynamic connections as defined above. These connecting elements are intended to connect at least two implantable connection assemblies.

[0051] The connecting element (1) illustrated in figure 1 consists of a cable (2) surrounded by a relatively flexible envelope (3). The said cable (2) for its part consists of an elastic strand or stem.

[0052] Strand means a strand consisting either of a single piece ("monostrand") or of several fibres.

[0053] Advantageously, the said strand is coaxial with the said envelope (3) so as to constitute the central core of the said connecting element (1).

[0054] Hereinafter, the said cable (2) will be referred to as the "central strand", and will also be referenced under the number (2).

[0055] The said envelope (3) consists of a flexible polymer, such as polyurethane or PEEK (polyetheretherketone). In a particular configuration of the invention, the said sheath is a biocompatible fabric.

[0056] In parallel, in order to offer the necessary return in order to oppose the pivoting movements of the vertebrae around these discs, the said cable, when it comprises only a single

strand, advantageously consists of a titanium alloy, PEEK, or a superelastic alloy of the nickel/titanium alloy type, also known by the name Nitinol®.

[0057] In order to improve the characteristic relating to the elasticity of the connecting element, one or more layers of successive strands are disposed around the said central strand (2).

[0058] Figures 2 and 3 illustrate in particular a connecting element (1) comprising a layer (4) of 6 strands (40) distributed around the said central strand (2).

[0059] Advantageously, the said strands (40) are disposed twisted around the said central strand (2).

[0060] According to another preferential embodiment of the invention, the said connecting element (1) is characterised in that it comprises a second layer of strands, advantageously consisting of 12 strands, and surrounding the said first layer (4) of 6 strands (40).

[0061] These two configurations of layers are here given by way of example. It is of course obvious to a person skilled in the art that the organisation and number of layers of strands, and the number of strands per layer and their configuration, will depend on the rigidity (or elasticity) required for the said connecting element (1).

[0062] However, the choice of the form and constitution of the cable will be guided by the constraint of the diameter, the purpose being to produce a connecting element with a small diameter (preferably less than or equal to 6 mm) so that the connecting element is as little invasive as possible.

[0063] Just like the central strand (2), the strand of each of the layers are made from elastic materials. Advantageously, the strands constituting the third layers and the central strand (2) are formed from titanium, stainless steel or PEEK.

[0064] It should be noted however that it is however not necessary for the strands constituting the said layers to be produced from the same material as that from which the said central strand (2) is produced.

[0065] Likewise, the said central strand (2) can also have a form or dimensions different from that of the strands constituting the said layers. In particular, according to a particular configuration of the invention, the said central strand (2) consists of a tube. In this case, the said central strand is preferably made from PEEK, the strands of the said layers being made from titanium or stainless steel.

[0066] Figure 4 illustrates a partial view in perspective of a spinal fixing system (100).

[0067] The said fixing system comprises a plurality of implantable connection assemblies. Only three of these implantable connection assemblies are shown in figure 4, these three connection assemblies being respectively referenced 110, 120, 130.

[0068] Each connection assembly is respectively connected to an adjoining connection assembly by a connecting element. In particular, in this example embodiment, the connection assembly (110) is connected to the connection assembly (120) by means of a spinal osteosynthesis connecting element, the connection assembly (120) being connected to the connection assembly (130) by means of a dynamic connecting element according to one of the embodiments illustrated in figures 1 to 3.

[0069] The combination of dynamic connecting elements and spinal osteosynthesis connecting elements thus makes it possible to offer a modular fixing system comprising conventional connecting elements of the osteosynthesis connection type and dynamic connecting elements.

[0070] Figure 5 illustrates a view in section of a connecting element (10) according to a preferred embodiment of the invention. The said connecting element (10) is advantageous in that it constitutes a "semi-dynamic" connection.

[0071] The said connecting element (10), in the form of a rod, consists of a flexible part (11) and a rigid part (12), the said rigid part (12) being fixed in line with the said flexible part (11). The "semi-dynamic" behaviour of the said connecting element (10) is conferred by each of the parts (11, 12), the flexible part (11) fulfilling the role of dynamic connection and the rigid part (12) the role of osteosynthesis connection.

[0072] Advantageously, the said flexible part (11) consists of a cable (13) at least partly surrounded by a polymer envelope (14), the said cable (13) consisting of at least one elastic strand coaxial with the said envelope (14). The said cable (13) has at one of its ends a bared zone (17) of the said envelope (14).

[0073] The rigid part (12) has a blind cavity (15) in which the bared zone (17) of the said cable (13) comes to be housed. Advantageously, the said cavity (15) is configured so as to permit close cooperation with the said cable (13).

[0074] Through its constitution and its function, the said flexible part (11), and therefore the said cable, is regularly subjected to oscillations. However, such a movement generates a risk of shearing of the said cable (13).

[0075] This is because the said cable (13) is bent against the cutting edges formed by the lateral walls of the said cavity (15) and the face constituting the end of the rigid part (12). Thus, and in order to limit this risk of shearing, the said cavity (15) has, on the emerging end, a widened zone (16).

[0076] The principle for producing the said connecting element (10) is as follows.

[0077] The said blind cavity (15) is formed longitudinally in the rigid part (12) by piercing. The cable (13) is then introduced into the said cavity (15) until it reaches the closed end of the said cavity (15). The part of the cable (13) inserted in the cavity (15) is fixed therein by adhesive bonding or crimping. Once the cable (13) is disposed and fixed in the cavity (15) in the rigid part (12), the final step consists of forming the envelope (14) by injecting a polymer around the part of the cable (13) not inserted in the cavity (15).

[0078] Advantageously, the said connecting element (10) is produced so that the said cable (13) is coaxial with the rigid part (12).

[0079] As in the examples described above, the said cable (13) consists either of a single elastic strand or an elastic strand surrounded by one or more successive layers of strands, the said strands of the said layers advantageously being twisted.

[0080] Moreover, the description given above relating to the constitution and configuration of the central strand and of the strands in the layers also applies in the context of this configuration.

[0081] Moreover, it is naturally evident that the semi-dynamic connecting element (10) is not limited to the configuration illustrated in figure 5. This is because it is naturally evident that the flexible part can advantageously be extended on each side by a rigid part.

[0082] Likewise, in the case of a multilevel vertebrae fixing and stabilisation system, the strand of the flexible part and of the rigid part or parts will depend on the type of connection required between each adjacent vertebra.

[0083] Finally, the dynamic connecting element can advantageously be formed by a plurality of flexible parts separated from one another by a rigid part.

[0084] The invention is described above by way of example. Naturally a person skilled in the art is in a position to implement different variants of the invention without for all that departing from the scope of the patent.